UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *County of Suffolk v. Abbott Labs., et al.*, (E.D.N.Y. No. CV-03-229)	

THE JOHNSON & JOHNSON DEFENDANTS' SEPARATE RESPONSE TO SUFFOLK COUNTY'S SUPPLEMENTAL FILING IN RESPONSE TO THE COURT'S OCTOBER 26, 2004 ORDER

Suffolk County's response to the Court's October 26, 2004 Order is improper and inadequate for the reasons set forth in the collective response submitted on behalf of the "Suffolk 13 + 6." As detailed in that submission, there are a host of methodological problems with Suffolk's "spread" calculations. Moreover, Suffolk has failed to comply with the Court's Order directing it to provide the documents it used to make those calculations. The Johnson & Johnson Defendants[1] join in the collective response for all of the reasons stated therein.

Separately, Suffolk tries to justify its allegations against the Johnson & Johnson Defendants by submitting "additional information" in an affidavit from counsel. The affidavit lists the reasons why Suffolk thinks it should be allowed to proceed against Johnson & Johnson, notwithstanding the absence of particularized allegations in the Amended Complaint:

1. "The Johnson & Johnson defendants have been sued in the AMCC and by the City of New York and the Counties of Rockland and Westchester." (Hovan Aff., ¶ 30).

2. "In addition, in connection with the wrongful conduct described in the Suffolk matter, the J&J defendants have been investigated by the General Accounting Office and the Office of the Attorney General for the Commonwealth of Massachusetts." (*Id.*).

3. "J&J is also being sued by the Pennsylvania Attorney General in connection with the same wrongdoing at issue in the Suffolk matter." (*Id.*, ¶ 31).

4. "J&J is among the pharmaceutical companies now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements." (*Id.*, ¶ 32).

5. "J&J is the subject of a Senate Finance Committee investigation regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements." (*Id.*, ¶ 33).

In addition, Suffolk attaches an unsworn exhibit in which it states that a "2001 GAO report confirms fraudulent AWP's for Johnson & Johnson's Procrit." (*Id.*, Ex. A).

---

[1] The Johnson & Johnson Defendants consist of Johnson & Johnson, Janssen Pharmaceutica Products, L.P., Ortho Biotech Products, L.P, and Ortho-McNeil Pharmaceuticals, Inc.

Suffolk's papers do not justify further proceedings against the Johnson & Johnson Defendants. First, the fact that certain Johnson & Johnson companies have been sued by other plaintiffs, including other counties represented by Suffolk's counsel, obviously does not mean that the claims against the Johnson & Johnson Defendants have merit. Indeed, there are several AWP-related cases in which the Johnson & Johnson Defendants have *not* been sued. The litigation landscape is irrelevant.

As for the government "investigations" identified in counsel's affidavit, suffice it to say that the Johnson & Johnson Defendants have responded to each entity's request for information and none of them have found that the Johnson & Johnson Defendants engaged in misconduct. For example, it has been years since Johnson & Johnson received and responded to a document request from the Massachusetts Attorney General. The Attorney General has not contacted Johnson & Johnson about it since. It may be that the governmental entities that requested information have concluded that the Johnson & Johnson Defendants did not engage in misconduct, or it may be that they have not reached a conclusion one way or the other. Regardless, the existence of investigations directed to multiple companies cannot support a claim of wrongdoing against any of them.[2]

Suffolk's most outrageous claim is that the General Accounting Office determined in 2001 that Procrit's AWP was "fraudulent." (Hovan Aff., Ex. A at A-3). Procrit is sold by Ortho Biotech Products, L.P., a Johnson & Johnson company that markets biotechnology products. Procrit is used to treat anemia. *See* http://www.procrit.com.

---

[2] For example, the Senate Finance Committee requested pricing information from 19 drug companies with respect to eight classes of drugs. The 19 companies were selected because they were "industry leaders in sales in 2003," and the eight drug classes were selected because they were the "top sellers in 2003." *See* April 29, 2004 Press Release regarding the Senate Finance Committee's inquiry into nominal price exceptions, *available at* http://finance.senate.gov/press/Gpress/2004/prg042904a.pdf.

Suffolk's characterization of the GAO report is wildly inaccurate. The GAO did not confirm that Procrit's AWP was "fraudulent." Rather, the report merely concluded, as had numerous prior reports, that "Medicare's payments for part B-covered drugs [including Procrit] were significantly higher than the physicians' and other providers' actual cost of acquiring these products." This unremarkable finding does not imply "fraud" or any other form of misconduct. AWP is not acquisition cost. Indeed, the GAO report describes AWP as a "'list price,' or 'sticker price,' or 'suggested retail price,'" which is "not necessarily the price paid by a purchaser or a consistently low or 'wholesale' price." The GAO did not conclude that AWPs that were higher than acquisition cost were "fraudulent," and the GAO certainly did not reach that conclusion with respect to Procrit. *See* "Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost," *available at* http://www.gao.gov/new.items/d011118.pdf.

Finally, one the many infirmities in Suffolk's method of calculating "spreads" is illustrated by the example of Duragesic®, a Johnson & Johnson medicine sold by Janssen Pharmaceutica Products, L.P. Suffolk did not find Duragesic prices at the retail web sites it consulted. Remarkably, Suffolk appears to have concluded from this that Duragesic's "true AWP" is "$0.00." (Hovan Aff., Ex. B at B-1). Based upon this assumption, Suffolk estimated that the "overcharge" on Duragesic is "100%." (*Id.*).

Suffolk's calculation of Duragesic's "spread" is obviously erroneous. Suffolk did not find Duragesic prices at retail web sites because Duragesic typically is not sold on the Internet. Duragesic contains a derivative of opium known as fentanyl. Fentanyl is a Schedule II narcotic used to treat certain forms of chronic pain. *See* 21 U.S.C. § 812 (list of Schedule II products); 21 U.S.C. § 812(c)(b)(6); 21 C.F.R. § 1308.12(c)(9). Because of its potential for

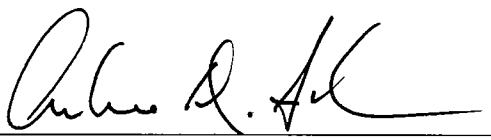
abuse, the distributing, prescribing and dispensing of fentanyl is tightly regulated and controlled by the Drug Enforcement Administration.

Drug products containing fentanyl, such as Duragesic, may only be dispensed by a DEA-registered pharmacy pursuant to a written prescription issued by a DEA-registered practitioner. A pharmacist may not fill the prescription without verifying the legitimacy of the prescription with the patient's physician. *See* 21 U.S.C. § 829(a) (limitations on dispensing of Schedule II products). Given these and other restrictions, it is not surprising that Duragesic prices were not available on retail websites.

* * *

Suffolk disregarded the Court's Order requiring it to provide copies of the documents it used to calculate the spread on Johnson & Johnson's products. Its claims against the Johnson & Johnson Defendants should be dismissed.

Respectfully submitted,



William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
Tel: (212) 336-2000
Fax: (212) 336-2222

Counsel for Johnson & Johnson, Janssen Pharmaceutica Products, L.P., Ortho Biotech Products, L.P, and Ortho-McNeil Pharmaceuticals, Inc.

Dated: November 30, 2004